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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,440	10/16/2001	Michael Greenstein	10004416	5699

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,440	GREENSTEIN ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2005 has been entered.

Election/Restrictions

Claims 21-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention of claims 21-22 and the invention of claims 1-19 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as heating and monitoring an array of zones that is not used as an analytical device (but rather to produce proteins or DNA, or to move materials in a channel for separation/purification purposes, for example.)

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21 and 22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

I. Claims 1, 10-12 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Zou et al., 6,762,049.

As to claim 1, Zou et al. disclose a cartridge ((1 and 2), see fig. 1) comprising one or more portions constructed of a material, wherein the one or more portions define an array of temperature-controlled zones ((chambers 6), see col. 2, line 67) including reactants (col. 4, line 13), and wherein each said temperature-controlled zone is constrained by cartridge portions that surround an area of space in which a reactant is

contained and confine the reactant from flowing into other of said temperature-controlled zones (fig. 3, disclosing each chamber 6 to be isolated from other chambers);

an array of heat source ((13), see fig. 4) wherein the array of heat sources is positioned to correspond to the array of temperature-controlled zones so that each heat source is arranged to provide temperature regulation to a corresponding temperature-controlled zone, and wherein one or more of the heat sources emit localized radiation to provide heating in the corresponding temperature-controlled zones (col. 2, lines 63-67, disclosing an array of blocks for each chamber (6), and col. 3, lines 63-66, disclosing heater and sensor (13) on the top of each block (1));

a temperature monitor that monitors reactant temperature (sensor 13, col. 64); and

a modulator that modulates the array of heat sources to regulate temperature in one or more of the corresponding temperature-controlled zones (col. 2, lines 42-43, disclosing individually controlled heaters and sensors);

whereby each temperature-controlled zone is controllable to a designated temperature (col. 1, lines 53-54, and col. 2, lines 42-43, disclosing independently and individually controlled heaters and sensors).

As to claim 10, the array of heat sources comprises internal heat generators (13).

As to claim 11, the internal heat generators comprise resistive heaters (col. 5, lines 14-15), inductive heaters or Peltier heaters.

As to claim 12, an array of electrical leads (16, col. 3 line 66 – col. 4, line 1) correspond with the internal heat generators.

As to claim 14, a power supply drives current to increase the temperature of the zones (col. 2, lines 42-43, and col. 5, lines 14-15).

As to claim 15, a controller coupled to said power supply controls the drive current (col. 2, lines 42-43, and col. 5, lines 14-15).

As to claim 16, the controller modulates the power supply based on a temperature measured from the temperature-controlled zones (col. 2, lines 42-46.)

As to claim 17, an array of temperature monitors is positioned to correspond to the array of temperature controlled zones (col. 3, line 64.)

As to claim 18, said reactants comprise assay elements for body fluid analysis (col. 1, lines 12-13, and lines 52-59.)

II. Claims 1, 10-12 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Burns et al., 6,379,929.

Burns et al. disclose a cartridge (silicon wafer, fig. 2B, including hundreds or thousands of substrates 300, col. 21, lines 50-51 and lines 60-62, and fig. 2A and 2B) comprising one or more portions constructed of a material, wherein the one or more portions define an array of temperature-controlled zones (microchannels 100 within each substrate 300) including reactants (col. 5, line 1), and wherein each said temperature-controlled zone is constrained by cartridge portions that surround an area of space in which a reactant is contained and confine the reactant from flowing into other of said temperature-controlled zones (see fig. 2A and 2B, and see col. 2, lines 50-

51, and lines 60-63, and col. 17, lines 59-61, disclosing a silicon device comprising a plurality of mcirofluidic device modules);

an array of heat source (resistors for each reaction chamber, col. 4, line 7) wherein the array of heat sources is positioned to correspond to the array of temperature-controlled zones so that each heat source is arranged to provide temperature regulation to a corresponding temperature-controlled zone, and wherein one or more of the heat sources emit localized radiation to provide heating in the corresponding temperature-controlled zones (see col. 3, line 66 – col. 4, line 7, disclosing heat resistors for each reaction chamber, and col. 17, lines 59-61, disclosing a silicon device comprising a plurality of microflidic device modules, thereby disclosing an array of heat source on the silicon device);

a temperature monitor that monitors reactant temperature (col. 4, lines 7-8, disclosing feed-back temperature detectors); and

a modulator that modulates the array of heat sources to regulate temperature in one or more of the corresponding temperature-controlled zones (col. 4, lines 5-17, disclosing a computer program to control the heat based on the heat detected by the temperature detector);

whereby each temperature-controlled zone is controllable to a designated temperature (col. 4, lines 14-17).

As to claim 10, the array of heat sources comprises internal heat generators (col. 4, line s 6-7.)

As to claim 11, the internal heat generators comprise resistive heaters (col. 4, lines 5-7), inductive heaters or Peltier heaters.

As to claim 12, an array of electrical leads correspond to the internal heat generators (col. 4, line 8.)

As to claim 14, a power supply drives current to increase the temperature of the zones (col. 4, lines 5-17).

As to claim 15, a controller (computer program, col. 4, lines 14-15) coupled to said power supply for controlling the drive current is disclosed.

As to claim 16, the controller modulates the power supply based on a temperature measured from the temperature-controlled zones (col. 4, lines 5-17, disclosing feed-back temperature detector, and a computer program to control the temperature of the reaction chamber.)

As to claim 17, an array of temperature monitors is positioned to correspond to the array of temperature controlled zones (col. 3, line 66 – col. 4, lines 7-8, disclosing feed-back temperature detector for each substrate.)

As to claim 18, said reactants comprise assay elements for body fluid analysis (col. 9, lines 45-47.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

III. Claims 2, 6-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Austin et al., 6,203,683.

Zou et al. disclose the invention substantially as claimed (see above), except for the heat sources being electromagnetic radiation emitters. Austin et al. however disclose electromagnetic radiation emitters.

Austin et al. teach a chip with an array of trapping electrode (col. 7, lines 23-25) wherein the electrode is a resistive heater (col. 3, line 66 – col. 4, line 2). Austin et al. also teach that as an alternative to a trapping wire, heating can be achieved by a Peltier device, or infrared light sources shining directly on the chip (col. 8, line 10-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide infrared light sources as an alternative to the resistive heaters in the Zou et al. device because Austin et al. teaches that infrared light sources are an alternative to resistive heaters for heating reactants in a chip.

Also, as to claims 8 and 9, neither Zou et al. nor Austin et al. disclose that the light sources generate infrared light with a wavelength of at least .775 micrometers, or at most 7000 micrometers.

Austin et al. teach that the heaters are intended for controlling the temperature for polymerase chain reaction for nucleic acid amplification (see column 1, lines 55-59.) It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In

re Aller, 1-5 USPQ 233. In this case, Zou et al. in view of Austin et al. disclose the general conditions of the claims, and infrared light with a wavelength as claimed is a workable range and thus its discovery only involves routine skill in the art.

IV. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zou et al., 6,762,049, in view of Austin et al., 6,203,683, as applied to claim 2, and further in view of Miyazaki et al., 5,599,502.

Zou et al. in view of Austin et al. disclose the invention substantially as claimed (see above), except for the infrared light source being a laser. (Austin et al. teaches an infrared light source but does not specifically disclose that the light source is a laser.)

Miyazaki et al. discloses a heat source producing infrared light for heating liquid during a reaction can be an infrared laser (col. 6, lines 23-28, and col. 9, lines 4-34.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an infrared laser as taught by Miyazaki et al. as the infrared light source in the Zou et al. invention because Miyazaki et al. teach that a laser producing infrared light provides the advantage of heating liquid during a reaction, such as the reaction in the Zou et al. invention.

V. Claims 2-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al., 6,379,929, in view of Austin et al., 6,203,683.

Burns et al. disclose the invention substantially as claimed (see above), except for the heat sources being electromagnetic radiation emitters. Austin et al. however disclose electromagnetic radiation emitters.

Austin et al. teach a chip with an array of trapping electrode (col. 7, lines 23-25) wherein the electrode is a resistive heater (col. 3, line 66 – col. 4, line 2). Austin et al. also teach that as an alternative to a trapping wire, heating can be achieved by a Peltier device, or infrared light sources shining directly on the chip (col. 8, line 10-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide infrared light sources as an alternative to the resistive heaters in the Burns et al. device because Austin et al. teaches that infrared light sources are an alternative to resistive heaters for heating reactants in a chip.

Also, as to claims 8 and 9, neither Burns et al. nor Austin et al. disclose that the light sources generate infrared light with a wavelength of at least .775 micrometers, or at most 7000 micrometers.

Austin et al. teach that the heaters are intended for controlling the temperature for polymerase chain reaction for nucleic acid amplification (see column 1, lines 55-59.) It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 1-5 USPQ 233. In this case, Burns et al. in view of Austin et al. disclose the general conditions of the claims, and infrared light with a wavelength as claimed is a workable range and thus its discovery only involves routine skill in the art.

VI. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al., 6,379,929, in view of Austin et al., 6,203,683, as applied to claim 2, and further in view of Miyazaki et al., 5,599,502.

Burns et al. in view of Austin et al. disclose the invention substantially as claimed (see above), except for the infrared light source being a laser. (Austin et al. teaches an infrared light source but does not specifically disclose that the light source is a laser.)

Miyazaki et al. discloses a heat source producing infrared light for heating liquid during a reaction can be an infrared laser (col. 6, lines 23-28, and col. 9, lines 4-34.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an infrared laser as taught by Miyazaki et al. as the infrared light source in the Burns et al. invention because Miyazaki et al. teach that a laser producing infrared light provides the advantage of heating liquid during a reaction, such as the reaction in the Burns et al. invention.

Response to Arguments

Applicant's argument regarding the restriction requirement has been fully considered but are not persuasive.

Applicant states that a shift to prosecution of claims 21-22 results in no additional work and also simplifies prosecution to a reduced number of claims. Applicant states that since a new search must be performed in the instant RCE application, Applicant

requests that Examiner allow a shift [of invention] in this case. This is not persuasive because during prosecution of the RCE application, the shift in invention may not necessarily simplify prosecution because additional claims and/or limitations may be added that substantially changes the scope of the invention.

Applicant also submits that the Office has not provided an example of a materially different process and requests a specific example of such use alleged by the Office. As mentioned above, some examples of methods of use that is different from the claimed process are a process of producing proteins or DNA, or moving materials in a channel for separation/purification purposes.

Applicant's argument with respect to the rejections of the above claims are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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09/13/05